"Express Mail" mailing label number

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Date of Deposit

January 23, 2004

Our Case No. 11320/33

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Miles B. Brennan et al.

Serial No: Not Assigned

Examiner: Angell, Jon E.

Filed:

Group Art Unit: 1635

For: Method for Treatment of Insulin

Resistance in Obesity and Diabetes

#### INFORMATION DISCLOSURE STATEMENT

COMMISSIONER FOR PATENTS , ALEXANDRIA, VA 22313-1450

Dear Sir:

In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Information Disclosure Statement be entered and the documents listed on the attached Form PTO-1449 be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g),(h), this Information Disclosure Statement is not to be construed as a representation that a search has been made and is not to be construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

This Information Disclosure Statement is being filed before the mailing of the first Office Action on the merits and hence is believed to be timely filed in accordance with 37 C.F.R. § 1.97(b). No fees are believed to be due in connection with filing of this Information Disclosure Statement. Should any additional fees under 37 C.F.R. §§ 1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Commissioner is hereby authorized to deduct said fees from Brinks Hofer Gilson & Lione Deposit Account No. 23-1925. A duplicate copy of this document is enclosed.

This application is a division of U.S. Patent Application Serial Number 09/953,349 which claims benefit of provisional application U.S. Application Serial No. 60/232,292, filed September 13<sup>th</sup>, 2000. This prior application is relied upon for an earlier filing dated under 35 U.S.C. § 119. In accordance with Rule 37 C.F.R. § 1.98(d) copies of the following documents cited are not enclosed:

A1	Beck-Nielsen, Henning and Groop, Leif C., Metabolic and Genetic Characterization of
ł	Prediabetic States: Sequence of Events Leading to Non-insulin-dependent Diabetes Mellitus,
	The Journal of Clinical Investigation, Vol. 94, pp. 1714-1721, 11/94.
A2	Stern, Michael P. and Mitchell, Braxton D. Genetics of Insulin Resistance, IN: Insulin
	Resistance, The Metabolic Syndrome X, Reaven, Gerald M. and Laws, Ami (Eds), Humana
	Press Inc., Totowa, NY, pp. 3-18, 2001.
A3	Després, Jean-Pierre and Marett, André. Obesity and Insulin Resistance, Epidemiologic,
	Metabolic, and Molecular Aspects, IN: Insulin Resistance, The Metabolic Syndrome X, Reaven,
	Gerald M. and Laws, Ami (Eds), Humana Press Inc., Totowa, NY, pp. 51-81, 2001.
A4	Fan, Wei, et al., The Central Melanocortin System Can Directly Regulate Serum Insulin Levels,
	Endocrinology, Vol. 141, pp. 3072-3079, 2000.
A5	Saltiel, Alan R. The molecular and physiological basis of insulin resistance: emerging
	implications for metabolic and cardiovascular diseases, The Journal of Clinical Investigation,
	Vol. 106, pp. 163-164, 07/2000,
A6	Cone, Roger D. Haploinsufficiency of the melanocortin-4 receptor: part of a thrifty genotype?
	The Journal of Clinical Investigation, Vol. 106, pp. 185-187, 07/2000.
A7	Kadowaki, T. Insights into insulin resistance and type 2 diabetes from knockout mouse models.
	The Journal of Clinical Investigation, Vol. 106, pp. 459-465, 08/2000.
A8	Obici, Silvana, et al., Central melanocortin receptors regulate insulin action, The Journal of
<u>.</u>	Clinical Investigation, Vol. 108, pp. 1079-1085, 10/01.
A9	Hani, El Habib, et al., Naturally Occurring Mutations in the Melanocortin Receptor 3 Gene Are
	Not Associated with Type 2 Diabetes Mellitus in French Caucasians, The Journal of Clinical
	Endocrinology & Metabolism, Vol. 86, pp. 2895-2898, 2001.

A10	Itagaki, Eiji, et al., Increases in Plasma ACTH and Cortisol after Hypertonic Saline Infusion in Patients with Central Diabetes Insipidus, The Journal of Endocrinology & Metabolism, Vol. 86, pp. 5749-5754, 2001.
A11	Arslanian, Silva A., et al., Metformin Therapy in Obese Adolescents with Polycystic Ovary Syndrome and Impaired Glucose Tolerance: Amelioration of Exaggerated Adrenal Response to Adrenocorticotropin with Reduction of Insulinemia/Insulin Resistance, The Journal of Clinical Endocrinology & Metabolism, Vol. 87, pp. 1555-1559, 2002.
A12	Jayagopal, V., et al., <i>The biological Variation of Insulin Resistance in Polycystic Ovarian</i> Syndrome, The Journal of Clinical Endocrinology & Metabolism, Vol. 87, pp. 1560-1562, 2002.
A13	Wang, H. et al., <i>Human Resistin Gene: Molecular Scanning and Evaluation of Association with Insulin Sensitivity and Type 2 Diabetes in Caucasians</i> , The Journal of Clinical Endocrinology & Metabolism, Vol. 87, pp. 2520-2524, 2002.
A14	Garg, Abhimanyu and Misra, Anoop. <i>Editorial: Hepatic Steatosis, Insulin Resistance, and Adipose Tissue Disorders</i> , The Journal of Clinical Endocrinology & Metabolism, Vol. 87, pp. 3019-3022, 2002.

If, for any reason, the Examiner feels that an interview would be helpful to resolve any issues, he is respectfully requested to contact the undersigned attorney at (312) 321-4229.

Respectfully submitted,

Date: January 23,2004

John Murray, Ph.D. Registration No. 44,251 Attorney for Applicant

BRINKS HOFER GILSON & LIONE P.O. Box 10395 Chicago, IL 60610 (312) 321-4200

FORM PTO-1449	SERIAL NO. Not assigned	CASE NO. 11320/33
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	FILING DATE	GROUP ART UNIT
(use several sheets if necessary)	APPLICANT(S): Brennan et al.	<u> </u>

### REFERENCE DESIGNATION

### **U.S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS/ SUBCLASS	FILING DATE

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS/ SUBCLASS	TRANS YES	LATION NO
					-	

	OTHER ART (Including Author, Title, Date, Pertinent Pages, etc.)
A1	Beck-Nielsen, Henning and Groop, Leif C., Metabolic and Genetic Characterization of
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	A3 A4 A5 A6 A7 A8 A9

EXAMINER	DATE CONSIDERED	

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FORM DTO 4440		Page 2 01 2
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